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EXAMINER	
KASSA, TIGABU	

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1619	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/583,440	KUHAR ET AL.	
	Examiner	Art Unit	
	TIGABU KASSA	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05/14/10, 02/16/2010, and 04/16/2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-12,14 and 16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-12,14 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/14/10 has been entered.

Formal Matters

Applicants' amendment and miscellaneous letter filed on 02/16/2010 and 04/16/2010 are acknowledged and entered due to request for continued examination. **Claims 1-5, 7-12, 14, and 16 are pending. Claims 1-5, 7-12, 14, and 16 are under consideration in the instant office action.** Claims 6, 13, and15 are cancelled. Applicants' amendment has necessitated a new ground of rejections under 35 U.S.C. 103(a).

Moot Rejections/Objections

All rejections and/or objections of claims 6, 13, and 15 cited in the previous office action mailed on November 16, 2009 are moot, because said claim(s) has/have been cancelled.

Rejections Withdrawn

All rejections applied in the previous office action are hereby withdrawn as a result of applicants claim amendments.

Note: Applicants' arguments filed on the miscellaneous letter on 04/16/2010 have been fully considered and are persuasive. Indeed Eudragit NE30D and Eudragit L30D-55 are different wherein the former is a pH independent polymer while the latter one is pH dependent polymer.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). Applicants' claim of foreign priority to Slovenia P-200300317 is DENIED because no English translation of the Slovenia P-200300317 document has been provided. Benefit is accorded to PCT/SI04/00044, filed on 12/22/2004.

New Rejections

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1-12, 14, and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Instant claim 1 incorporates a recitation of a phrase "which a low dosage of tamsulosin or pharmaceutically acceptable salt thereof which is freely soluble in water can be released in a controlled manner independently from pH thereby **providing a lower biological variability**". It is not clear what the phrase providing a lower biological variability is referring to. It is not clear what applicants are referencing or comparing to while reciting providing a lower biological variability

Instant claim 16 refers to the pharmaceutical formulation of cancelled claim 13. The examiner cannot ascertain what formulation applicants are referring to. The examiner cannot continue examination on the merits of claim 16 until the metes and bounds of the formulation referred to in the claim are specifically recited.

The other dependent claims are incorporated in the rejection as depending from indefinite base claims.

Applicant is also referred to *Ex parte Miyazaki* (BPAI 11/19/2008) (Homer, APJ) (precedential). A five member expanded panel of the Board held that "if a claim is amenable to two or more plausible claim constructions, the USPTO is justified in requiring applicant to more precisely define the metes and bounds of the claimed invention by holding the claim unpatentable under 35 USC 112, second paragraph, as indefinite." *Miyazaki*, slip op. at 11-12.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not

commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness

Claims 1-5, 7-8, 11-12, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buxton et al. (US Patent 5508044) in view of Cervenakov et al. (International Urology and Nephrology, 34, 25-29, 2002) and Jan et al. (Chinese Journal of Physiology, 4(14), 181-188, 1998) as evidenced by Chen et al. (US Patent 6602522).

Applicants Claim

Applicants claim a controlled release pharmaceutical formulation comprising a pellet core having a diameter from about 0.5 to about 2.00 mm from which a low dosage of tamsulosin, or a pharmaceutically acceptable salt thereof, which is freely soluble in water can be released in a controlled manner independently from pH thereby providing a lower biological variability, wherein said pellet core comprises at least one water insoluble permeable polymer and wherein said pellet core is coated with a gastroresistant and/or release controlling coating. Instant claim 2 recites similar subject matter as in claim 1 except that surfactant and optionally other excipients are added in the pellet core.

The dependent claims thereof recite types of polymers size of pellet cores, amounts of coatings, dosage forms, process of preparation, and method of treatments.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Buxton et al. teach a solid oral dosage form comprising diltiazem (or a pharmaceutically acceptable salt thereof) in controlled release form and hydrochlorothiazide in immediate release form (see abstract). Preferably, the controlled release component comprises a plurality of spheroids comprising diltiazem and a spheronizing agent (see abstract). Buxton et al. teach a solid oral dosage form for the treatment of hypertension in humans, comprising **a core comprising a plurality of spheroids comprising diltiazem or pharmaceutically acceptable salt thereof, and a spheronizing agent, wherein said diltiazem or pharmaceutically acceptable salt thereof is present in an amount effective to render an antihypertensive effect**, said **core including a water-insoluble material selected from the group consisting of a wax, an alkylcellulose and a polymethacrylate in an amount effective to prolong the release of said diltiazem over a desired period of time when said dosage form is contacted with water or digestive fluids**, wherein said **spheroids are coated with a controlled release film coating comprising from about 50% to about 95% ethylcellulose, from about 5% to about 15% dibutyl sebacate, and from about 5% to about 15% polysorbate 80**; and an immediate release coating on said core including an effective amount of hydrochlorothiazide to render a diuretic effect when said dosage form is contacted with water or digestive fluids (please see claim 1). The cellulose ether is preferably substituted cellulose ether such as **alkylcellulose** and is preferably a substituted alkylcellulose such as **ethylcellulose** or **hydroxy (C_1 to C_6) alkyl cellulose**,

such as **hydroxypropylcellulose**, **hydroxypropylmethylcellulose phthalate** and especially **hydroxyethylcellulose** (column 2, lines 33-38). Preferably the matrix contains between 2% and 60%, especially between 3% and 50% (by wt) of the cellulose ether) (column 2, lines 38-40). **The acrylic resin is preferably a methacrylate such as methacrylic acid copolymer USNF Type A (Eudragit L™), Type B (Eudragit S™), Type C (Eudragit L 100-55™), Eudragit NE 30D, Eudragit E, Eudragit RL and Eudragit RS** (column 2, lines 41-44). Preferably the matrix contain between 2% and 60% by weight, particularly between 3% and 50% by weight of the acrylic resin (column 2, lines 44-45). With regard to instant claim 4 the **Eudragit NE 30D** polymer is a copolymer of ethylacrylate and methylmethacrylate in a ratio of 2:1 as evidenced by Chen et al. Chen et al. teach that **polymethacrylic acid copolymer such as Eudragit NE30D (ethlacrylate/jmethylmehacrylate 2:1) is available as a 30% aqueous dispersion** (column 3, line 19-26). In addition to the above ingredients, the controlled release matrix may also contain suitable quantities of other materials, e.g. diluents, lubricants, binders, granulating aids, colorants, **surfactants**, anti-adherents, flavorants and glidants that are conventional in the pharmaceutical art (column 2, lines 66-67-column 3, lines 1-3). The term "bead" is conventional in the pharmaceutical art and means a spherical granule having a diameter of **between 0.1 mm and 2.5 mm, especially between 0.5 mm and 2 mm** (column 3, lines 13-15). The amount of controlled release coating material will depend on the desired release rate but is generally in the range of from **about 1% to about 25%, preferably from about 2% to about 8% by weight of the controlled release coated spheroid** (column 4, lines 32-36). **Buxton et al. teach the diltiazem containing spheroids according to the invention may be prepared by (a)**

granulating a mixture comprising diltiazem or a pharmaceutically acceptable salt thereof, water and optionally spheronizing agent; (b) extruding the granulated mixture to give an extrudate; (c) spheronizing the extrudate until spheroid cores are formed; (d) drying the spheroid cores; and, optionally, (e) film coating the spheroid cores (column 4, lines 37-47). With respect to the limitations of instant claim 2 Buxton et al. teach that optionally the spheroid core may also contain other pharmaceutically acceptable excipients and diluents which facilitate spheronization such as sugars (for example sucrose, dextrose, maltose or lactose) or sugar alcohols (for example mannitol, xylitol or sorbitol (column 3, lines 48-52). Specifically, Buxton et al. teach the incorporation of a surfactant cetostearyl alcohol in the core of illustrative example described in example 3 table 7. Buxton et al. also teach that the spheroid cores are preferably film coated with a material which permits release of the diltiazem at a controlled rate in an aqueous medium (column 3, lines 54-56). Suitable film coating materials include water insoluble waxes and polymers such as polymethacrylates (for example Eudragit polymers.TM.) or preferably water insoluble celluloses particularly ethylcellulose (column 3, lines 56-60). **This film coat may also include water soluble polymers such as polyvinylpyrrolidone or preferably a water soluble cellulose such as hydroxypropylmethylcellulose and hydroxypropylcellulose** (column 3, lines 60-63). It will be appreciated that the ratio of water insoluble to water soluble material will depend on the release rate required and the solubility of the materials selected (column 3, lines 63-66). The ratio of water soluble polymer to water insoluble polymer is preferably 1:20 to 1:2 (column 3, lines 66-67).

Ascertainment of the Difference between Scope the Prior Art and the Claims (MPEP §2141.012)

Buxton et al. do not explicitly teach the incorporation of tamsulosin or pharmaceutically acceptable salt thereof. This deficiency is cured by the teachings of Cervenakov et al. and Jan et al.

Cervenakov et al. teach alpha-1 blockers decrease the tension and release the spasm of smooth muscles and thus lessen the obstruction and irritation symptoms in the lower urinary tract (LUTS) (see abstract). They make a faster passing of calculi from the terminal part of ureters possible (see abstract). **Cervenakov et al. teach that administration of the alpha-1 blocker tamsulosin in patients suffering from ureterolithiasis registered a more speedy passing of calculi from the terminal parts of ureters** (see abstract). The transport of the stones from the kidney into the bladder and then their movement through the ureter is accompanied by three basic factors: spasm of smooth muscles, submucosal edema and pain (see introduction). **Determining factors are the size and configuration of the stones, their localization and numbers (see introduction). For instance during a treatment of Extracorporeal Shock Wave Lithotripsy (ESWL) angular stones cause considerable difficulties** (see introduction).

Jan et al. teach Shock Wave Lithotripsy (SWL) has become a modality for disintegrating kidney stones in treatment of ureterolithiasis (see introduction); **however a number of side effects exist** (see introduction). **In addition to hematomas and edema and a risk of hypertension, SWL causes renal function and alterations, including a transient decrease in filtration rate, an increased excretion of α1-and β2 microglobulin and N-acetyl-b-glucosaminidase, and a decreased excretion of Tamm-Horsfall protein** (see introduction page 181). Jan et al. teach that because the integrity of cell membrane was perturbed by shock wave exposure (SWE), implicated by increased

enzyme release, it is possible that there might be rise in $[Ca^{2+}]_i$. Since elevated $[Ca^{2+}]_i$ often associates with cell injury, if SWE causes a rise in $[Ca^{2+}]_i$ in the cells, it is possible that Ca^{2+} entry blockers such as nifedipine, verapamil, and **diltiazem** might protect the cells following SWE by inhibiting extracellular Ca^{2+} influx (see results page 183). **Jan et al. teach that their results suggest that the Ca^{2+} entry blockers could prevent the SWE-evoked rises in the resting $[Ca^{2+}]_i$ in MDCK cells** (see results page 184).

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the teachings of Buxton et al. via incorporating tamsulosin or pharmaceutically acceptable salt thereof in their composition because while **Cervenakov et al. teach that administration of the alpha-1 blocker tamsulosin in patients suffering from ureterolithiasis registered a more speedy passing of calculi from the terminal parts of ureters during for example shock wave exposure** (see abstract) and Jan et al teach that are caused by shock wave exposures during removal of kidney stones in **ureterolithiasis the side effects on the cells can be prevented by the use calcium entry blockers like diltiazem** (see introduction and results). One of ordinary skill in the art would have been motivated to incorporate tamsulosin or pharmaceutically acceptable salt thereof in the composition of Buxton et al. because while performing a shock wave exposure to disintegrate the calculi the passage of the pieces of calculi can be facilitated by the incorporation of tamsulosin by **decreasing the tension and release the spasm of smooth muscles and thus lessen the obstruction and irritation symptoms in the lower urinary tract (LUTS)** (see abstract)

while the **diltiazem in the composition of Buxton et al. protects the other side effects of the shock wave exposure described above.** One of ordinary skill in the art would be motivated to incorporate the tamsulosin in the controlled release formulation because the removal of the calculi would not occur instantaneously both relaxing the muscles and taking care of the side effects of the shock wave would be advantageous if they occurred in a prolonged manner. Applicants are using a product-by process format regarding the limitation in instant claim 12. The 35 USC 103 rejection set forth above is proper because the product-by-process format that applicant incorporated does not impart any structural difference with the prior art product since Buxton et al. follows same steps except that the drug tamsulosin is not incorporated in the formulation. It is to remedy this deficiency why Cervenakov et al. and Jan et al. are incorporated in the rejections. Please note that in product-by-process claims, "once a product appearing to be substantially identical and a 35 U.S.C. 103 rejection [is] made, the burden shifts to the applicant to show an unobvious difference." MPEP 2113. This rejection under 35 U.S.C. 103 is proper because the "patentability of a product does not depend on its method of production." *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtains prior art products and makes physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972). Please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants' composition as recited differs and, if so, to what extent, from that of the discussed references. Therefore, with the showing of the references, the burden of establishing non-obviousness by objective evidence is shifted to the

Applicants. With regard to the amount of coating material and the diameter or size of the core, in the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" aprimafacie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). Furthermore, differences in concentration or particle size of the core will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or particle size is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233,235 (CCPA 1955). One of ordinary skill in the art would have had a reasonable chance of success in combining the teachings of Buxton et al., Cervenakov et al. and Jan et al. because the Buxton et al. teach composition containing **diltiazem** and Jan et al. teach the use of **diltiazem** for protecting celles from side effects of shock wave exposure during removal of calculi. Furthermore, Cervenakov et al. teach the use of tamsulosin et al. for facilitating the passage of calculi during removal of calculi via the ureter by application of shock wave.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary

skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buxton et al. (US Patent 5508044) in view of Cervenakov et al. (International Urology and Nephrology, 34, 25-29, 2002) and Jan et al. (Chinese Journal of Physiology, 4(14), 181-188, 1998) as applied to claims 1-5, 7-8, 11-12, and 14 above, and further in view of Chen et al. (US Patent 6602522).

Applicant Claims

The claimed subject matter of instant claims 1 and 3 are set forth above. Instant claim 9 recites the pharmaceutical formulation according to claim 1 wherein the coating comprises at least one polymer soluble at pH values higher than about 5.5 and at least one polymer with a pH independent solubility. Instant claim 10 recites the formulation according to claim 9 wherein the polymers are an anionic copolymer of methacrylic acid and ethylacrylate and an ethylacrylate and methylmethacrylate copolymer, respectively.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Buxton et al., Cervenakov et al. and Jan et al. are set forth above.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Buxton et al. do not explicitly teach the inclusion the polymer soluble at pH values higher than 5.5 in the coating and that polymer being an anionic copolymer of methacrylic acid and ethylacrylate. These deficiencies are cured by the teachings of Chen et al.

Chen et al. teach a pharmaceutical composition comprising a core and a coating layer (abstract). The core contains a therapeutic active ingredient, **a surface active agent**, filler, an alkaline agent, and a binder (column 2, lines 10-20). The binder can be a water-insoluble polymer such as a **polymethacrylic acid copolymer such as Eudragit NE30D (ethlacrylate/jmethylmehacrylate 2:1) which is available as a 30% aqueous dispersion** (column 3, line 19-26). The enteric coating resists acid up to **about pH 5 or higher** (column 3, lines 48-50). Moreover, Chen et al. teach the same polymers as specified in instant claims 9 and 10 and the pH solubility of the polymer is an inherent property of the polymers. The coating, therefore, controls the release of the active agent. The coating preferably comprises a combination of polymers including, for example **Eudragit L30-55 (methacrylic acid and ethylacrylate) and Eudragit NE30D (ethlacrylate/methylmehacrylate 2:1)** (column 3, lines 48-58). The active ingredient and other ingredients for the core are combined, granulated, dried, formed into tablets, and coated (column 4, lines 20-33).

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time of the instant invention was made to modify the teachings of Buxton et al. via the incorporation of the polymer with solubility at pH values higher than 5.5 because Chen et al. teach a controlled release formulation of comprising the polymers. An ordinary skilled artisan would have been motivated to use the polymers with solubility at pH values higher than 5.5 because Chen et al. teach that such polymers can be used as an enteric coating agent since they can resist acids up to a pH of about 5 or higher (column

3, lines 48-50). An ordinary skilled artisan would have had a reasonable expectation of success upon combination of Buxton et al and Chen et al., because both references teach controlled release formulations of comprising a pellet core containing an active coated with a controlled release layer.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed.

This office action is Non-Final.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIGABU KASSA whose telephone number is (571)270-5867. The examiner can normally be reached on 9 am-5 pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne P. Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tigabu Kassa 08/11/10

/Cherie M. Woodward/
Primary Examiner, Art Unit 1647